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### **REMARKS**

#### **I. Claim Rejections – 35 USC § 112**

Claims 21 and 24 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the subject matter “second material includes barium sulfate particles” is not disclosed in the specification. Applicants respectfully disagree.

The Examiner’s attention is drawn to page 5, lines 6-8, which states that the distal tip includes tungsten carbide and the remaining sheath segments include barium sulfate particles. Accordingly, withdrawal of the rejection is respectfully requested.

#### **II. Claim Rejections – 35 USC§ 103**

Claims 1, 3-12, 14-19, 20, 22 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,171,295 to Garabedian et al. (“Garabedian”) in view of U.S. Patent No. 5,921,933 to Sarkis et al. (“Sarkis”). The Examiner’s rejection is respectfully traversed.

The present invention is directed to a guide catheter having a distal tip that is formed of a material causing the catheter to be both radio-opaque and echogenic. Even if, for the sake of argument, it is assumed, as suggested by the Examiner, that Garabedian teaches a reinforcing member comprising a radio-opaque material for use in a fluoroscopic procedure, and Sarkis teaches an echogenic portion of enhanced visibility in a procedure including an ultrasound scan, and even if it is assumed that there is a motivation to combine the two materials in a single catheter, if the separate teachings of Garabedian and Sarkis were combined in a single catheter to make the catheter both radio-opaque and echogenic, the catheter would not maintain the same mechanical and material properties, such as properties associated with the current loading of barium sulfate in the catheter, extrusion capabilities when forming the catheter,

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biocompatibility of the device when placed within the patient, along with the physical handling properties of the catheter, such as torqueability, stiffness, etc., since neither Sarkis or Garabedian teach or suggest the loading of the radio-opaque material and the echogenic material that would be required when the catheter is both radio-opaque and echogenic while maintaining current material and mechanical properties.

The inventors of the present invention have found that while it was previously known to form a guide catheter using a material having properties causing it to just be radio-opaque, or to form a guide catheter using a material having properties causing it to just be echogenic, no known catheter has previously been developed that was both radio-opaque and echogenic that still maintained properties associated with the known barium sulfate loading of the catheter, with the biocompatibility of the catheter, with extrusion capabilities associated with forming the catheter, along with the physical handling properties of the catheter, such as torqueability, stiffness, etc. The inventors have performed extension experimentation to develop a catheter having the necessary loading of materials that enables the catheter to be both radio-opaque and echogenic, while maintaining the current mechanical and physical properties.

Therefore, neither Garabedian nor Sarkis, alone or in combination, teach or suggest a guide catheter that is both radio-opaque and echogenic, as set forth in independent claims 1, 12 and 20 of the present invention. Therefore, claim 1 and claims 3-11 dependent thereon, independent claim 12 and claims 14-19 dependent thereon, and independent claim 20 and claims 21-23 dependent thereon are patentably distinguishable from Garabedian and Sarkis. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1, 3-12, 14-19, 20, 22 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0037065 to Graf et al. ("Graf") in view of Garabedian. The Examiner's rejection is respectfully traversed.

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As stated by the Examiner, Graf teaches an introducer distal tip that is radio-opaque. However, for reasons set forth above, neither Graf nor Garabedian, alone or in combination, teach or suggest a distal tip that is both radio-opaque and echogenic, as set forth in independent claims 1, 12 and 20 of the present invention. Therefore, claim 1 and claims 3-11 dependent thereon, independent claim 12 and claims 14-19 dependent thereon, and independent claim 20 and claims 21-23 dependent thereon are patentably distinguishable from Graf and Garabedian. Accordingly, withdrawal of the rejection is respectfully requested.

Furthermore, for reasons described above, none of the referenced prior art documents, alone or in combination, teach or suggest a first material forming the distal tip, wherein the first material is formed of a polymeric material and jet-milled tungsten carbide particles, and a second material forming a wall of the sheath and formed of a polymeric material and barium sulfate particles, with the jet-milled tungsten carbide particles distributed within the polymeric material of the first material between approximately 70 to 75 percent by weight and have an average diameter approximately less than or equal to 500 nanometers, as set forth in independent claim 24 of the present invention. Therefore, independent claim 24 is patentably distinguishable from the referenced prior art documents. Accordingly, allowance of Independent claim 24 is respectfully requested.

### III. Conclusion

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited.

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Finally, if there are any formal matters remaining after this Amendment, the Examiner is requested to telephone the undersigned attorney to attend to those matters.

Respectfully submitted,

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Date

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